/S/ [redacted]

Signature of PM/CSO
Date: 8/16/99

Signature of Division Director /S/ [redacted]
Date: 10/1/99

/S/ [redacted]
9/2/99

cc:
Original NDA
Division File
HFD-93 Mary Ann Holovac

BACK TO TOP

APPEARS THIS WAY ON ORIGINAL

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	20719	**Trade Name:**	PRELAY(TROGLITAZONE)TABS 200MG/400MG
Supplement Number:	12	**Generic Name:**	TROGLITAZONE
Supplement Type:	SE1	**Dosage Form:**	TAB
Regulatory Action:		**Proposed Indication:**	Provides for the use of troglitazone with metformin or with metformin and sulfonylurea in patients with type 2 diabetes.

ARE THERE PEDIATRIC STUDIES IN THIS SUBMISSION?

NO, No waiver and no pediatric data

What are the INTENDED Pediatric Age Groups for this submission?

____NeoNates (0-30 Days) ____Children (25 Months-12 years)

____Infants (1-24 Months) ____Adolescents (13-16 Years)

Label Adequacy	Does Not Apply
Formulation Status	
Studies Needed	
Study Status	

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? NO

COMMENTS:

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, JENA WEBER

/S/ [redacted]

Signature

/S/ [redacted]

8/16/99

Date

8/30/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-719/S-012

Sankyo U.S.A. Corporation
780 Third Avenue (47th Floor)
New York, NY 10017

JAN 25 1999

Attention: David L. Woodward, Ph.D.
Vice President, Development

Dear Dr. Woodward:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Prelay™ (troglitazone) Tablets

NDA Number: 20-719

Supplement Number: S-012

Date of Supplement: January 15, 1999

Date of Receipt: January 19, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on March 20, 1999, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/ [redacted]

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

PHONE: (212) 753-3172

FAX: (212) 308-2491

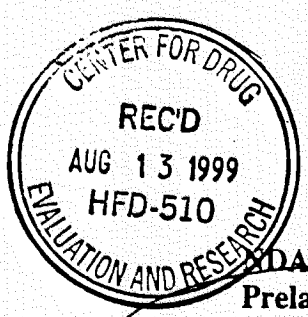
SANKYO U.S.A. CORPORATION

780 THIRD AVENUE, 47th FLOOR
NEW YORK, N.Y. 10017

ORIGINAL

August 12, 1999

NDA SUPP AMEND
SE1-012-BL



Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine
Drug Products (HFD-510)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

~~NDA 20-719/S-012~~
Prelay Tablets
Revised Labeling (PI) Supplement
(Metformin Efficacy) Amendment

Dear Dr. Sobel:

Please refer to our approved New Drug Application (NDA 20-719) for Prelay™ (troglitazone) Tablets.

On January 15, 1999, we submitted a supplement to the approved NDA, providing for a revision in the package insert, namely a new indication for the use of troglitazone with metformin or with metformin and sulfonylureas in patients with type 2 diabetes. This was an attempt to bring our NDA up to date with Parke-Davis' supplement (S-012) for Rezulin® Tablets (NDA 20-720) as amended. Parke-Davis' Rezulin package insert has been further revised in amendments dated December 8 and 15, 1998, and January 6, 11, 13, and 28, March 10, 18, and 31, May 4, and June 11 and 16, 1999. Their supplement was finally approved on June 16, 1999.

The purpose of this amendment is to bring our supplement (S-012) current with theirs. All data to support our amended supplement is included in the Parke-Davis supplement dated November 18, 1998, and the subsequent amendments noted above.

The revised PI (showing all changes) is enclosed (TAB 1). Please note that we have used the revised Prelay™ package insert included in our January 15, 1999, supplement as the starting point, and revised it to incorporate the subsequent changes made by Parke-Davis in the Rezulin® package insert approved June 16, 1999.

Additions are indicated by shading and deletions are indicated using the ~~strikethrough~~ font. Also enclosed (TAB 2) is a copy of the completed package insert, which incorporates all the insertions and deletions itemized in TAB 1. As indicated in our January 29, 1997, amendment to the unapproved NDA, the NDC numbers for Prelay™ will be added prior to market introduction of this product.

/S/

9/7

AP

Initial
/S/
9/22/99

Also enclosed is a copy of the "Dear Healthcare Professional" letter mailed by Parke-Davis (TAB 3).

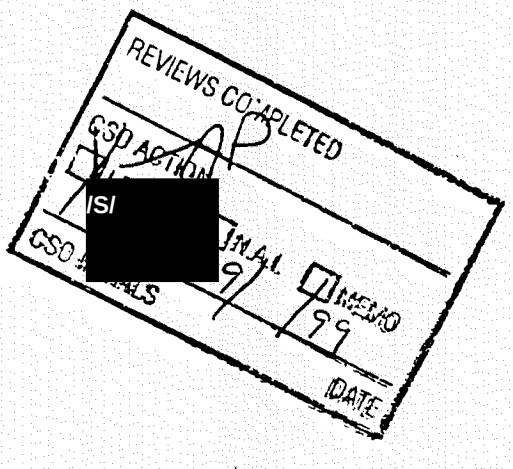
Should you have any questions regarding this submission, please contact me at 212-753-3172 or FAX 212-308-2491.

Sincerely,

David L. Woodward, Ph.D.
Senior Vice President, Development

Enclosures (3)
Revised Package Insert (showing all changes) (TAB 1)
Revised Package Insert (incorporating all changes) (TAB 2)
Dear Healthcare Professional letter (TAB 3)

[redacted]
8/10/99



DUPLICATE

PHONE: (212) 753-3172

FAX: (212) 308-2491

SANKYO U.S.A. CORPORATION

780 THIRD AVENUE, 47th FLOOR
NEW YORK, N.Y. 10017

NDA NO. 20-719 REF NO. 012

NDA SUPPL FOR 561

January 15, 1999

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine
Drug Products (HFD-510)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

JAN 1 9 1999

NDA 20-719
Prelay Tablets
Revised Labeling (PI) Supplement
(Metformin Efficacy)

Dear Dr. Sobel:

Please refer to our approved New Drug Application (NDA 20-719) for Prelay™ (troglitazone) Tablets. Pursuant to 21 CFR 314.70(b), enclosed is a supplement to the approved NDA, providing for a revision in the package insert.

On November 18, 1998, Parke-Davis submitted a supplement (S-012) to their NDA 20-720 for Rezulin® Tablets, providing a new indication for the use of troglitazone with metformin or with metformin and sulfonylureas in patients with type 2 diabetes. That supplement has not yet been approved.

The purpose of this supplement is to bring the Prelay™ NDA current with the Rezulin® NDA by also providing for a revised package insert for the same indication. All data to support our supplement is included in the Parke-Davis supplement dated November 18, 1998, and their amendments dated December 8 and 15, 1998, and January 6 and 11, 1999. The authorization for Sankyo U.S.A. Corporation to refer to the information contained in the Parke-Davis supplement is enclosed (TAB 1) (Parke-Davis letter dated January 6, 1999).

Although the Use Fee Cover Sheet included with this application indicates that clinical data are required for approval, no money accompanies this submission because of CDER's policy of only charging once for the review of the same data. We believe that because Parke-Davis has paid the entire fee with their application, none is due by Sankyo U.S.A. Corporation.

The revised PI (showing all changes) is enclosed (TAB 2). Please note that we have used the Prelay™ package insert included in our July 24, 1998 supplement (S-010) as the starting point, and revised it to incorporate the changes made by Parke-Davis in the Rezulin® package insert (S-011). Our S-010 supplement was submitted as a changes-being-effected supplement for which we have not yet received approval. We did not use the version of the package insert included in the Prelay™ supplement (S-011) submitted November 30, 1998, adding Geriatric

information because it was submitted as a regular supplement, and we have not received approval. Additions are indicated by shading and deletions are indicated using the ~~strikethrough~~ font. Also enclosed (TAB 3) is a copy of the completed package insert, which incorporates all the insertions and deletions itemized in TAB 2. The only variation with the Parke-Davis package insert is where they missed some changes of "type I" or "type II" diabetes to "type 1" and "type 2", respectively. The Prelay™ package insert includes those additional changes. As indicated in our January 29, 1997, amendment to the unapproved NDA, the NDC numbers for Prelay™ will be added prior to market introduction of this product.

As for the "Certification of Generic Drug Enforcement Act of 1992" (Item 13.2):

> Sankyo U.S.A. Corporation certifies that it is not debarred. Sankyo U.S.A. Corporation further certifies that it did not and will not use in any capacity the services of any person debarred under Section 306 of the Act, in connection with this application.

Marketing exclusivity information (Item 13.1) is enclosed as TAB 4.

Should you have any questions regarding this submission, please contact me at 212-753-3172 or FAX 212-308-2491.

Sincerely,

David L. Woodward, Ph.D.
Vice President, Development

Enclosures (5)

Authorization Letter from Parke-Davis dated January 6, 1999 (TAB 1)
Revised Package Insert (showing all changes) (TAB 2)
Revised Package Insert (incorporating all changes) (TAB 3)
Marketing Exclusivity Information (TAB 4)

NDA SUPP AMEND

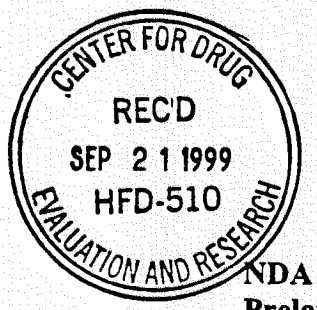
PHONE: (212) 753-3172

FAX: (212) 308-2491

SANKYO U.S.A. CORPORATION

780 THIRD AVENUE, 47th FLOOR
NEW YORK, N.Y. 10017

September 20, 1999



Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine
Drug Products (HFD-510)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

NDA 20-719/S-012
Prelay Tablets
Revised Labeling (PI) Supplement
(Metformin Efficacy) Amendment

Dear Dr. Sobel:

Please refer to our approved New Drug Application (NDA 20-719) for Prelay™ (troglitazone) Tablets and our revised PI supplement dated January 15, 1999, and amended August 12, 1999.

On September 20, 1999, you called and pointed out a few errors in the revised PI included in our August 12, 1999, amendment as follows (from the "Version Incorporating All Changes"):

Page 4, first paragraph under "Combination with Sulfonylureas" – [redacted] should be changed to [redacted] in the following: "[redacted]

Page 6, Table 5 – [redacted] should be deleted from the statement DRAFT LABELING [redacted]

I also changed the date of the package insert from "August 1999" to "September 1999."

These changes have been made and are included in the enclosed revised package insert.

Should you have any questions regarding this submission, please contact me at 212-753-3172 or FAX 212-308-2491.

Sincerely,

David L. Woodward, Ph.D.
Senior Vice President, Development

Enclosure
Revised Package Insert dated September 1999